

## REMARKS

Reconsideration of the present application in view of the above amendments and the following election is respectfully requested.

Claims 1-11, 19-27, 31-44 and 46-54 were pending. Claim 37 has been canceled without acquiescing to the rejections in the Office Action or prejudice to future prosecution in a related application. New claims 55-60 have been added. Accordingly, claims 1-11, 19-27, 31-36, 38-44, and 46-60 are pending.

Support for new claims 55 and 56 may be found, for example, in Figure 1 and page 4 of the clean version of the substitute specification submitted on February 27, 2009. Support for new claim 57 may be found in original claim 28. Support for new claims 58-60 may be found, for example, in the first full paragraph on page 13. More specifically, because SEQ ID NO:4 is 22 nucleotides in length, a hybridization probe composed of (a) SEQ ID NO:4 and (b) two sequences each of about 75% of the length of SEQ ID NO:4 that flank each side of SEQ ID NO:4 is about 56 nucleotides in length. Similarly, a hybridization probe composed of (a) SEQ ID NO:5 and (b) two sequences each of about 75% of the length of SEQ ID NO:5 that flank each side of SEQ ID NO:5 is about 46 nucleotides in length. Likewise, a hybridization probe composed of (a) SEQ ID NO:6 and (b) two sequences each of about 75% of the length of SEQ ID NO:5 that flank each side of SEQ ID NO:6 is about 47 nucleotides in length. Accordingly, no new matter has been added via the addition of the new claims.

Claims 1, 10, 19-27, 31, 33, 35, 36, 38-44, 46-49 and 51 have been amended. Such amendments have been made without acquiescing to the rejections in the Office Action or prejudice to future prosecution of previously pending claims. Support for the amendments to claim 1 may be found, for example, in original claim 1, Figure 1, and the first paragraph on page 4. Claim 10 has been amended to enter minor changes. Support for the amendments to claims 19 and 20 may be found, for example, in the first paragraph on page 4. Claims 21-27 have been amended to enter minor changes. Support for the amendments to claim 31 may be found, for example, in the first paragraph on page 4. Claim 35 has been amended to enter a minor change. Support for the amendments to claim 35 may be found, for example, in the fourth paragraph on page 16. Support for the amendments to claim 36 may be found, for example, in original claim

36, pages 4 and 5 and Examples 1 to 3. Claims 38-44 have been amended in view of the cancelation of claim 37. claims 46-49 and 51 have been amended to enter minor changes. No new matter has been added via the amendments to the claims.

Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 1-11 stand rejected under 35 U.S.C. 112, second paragraph, as indefinite. More specifically, it is asserted in the Office Action that the above claims are indefinite because they do not recite the polymorphism specific for *M. tuberculosis* in position -215.

To facilitate allowance and without acquiescing to the above rejection, Applicant has amended claim 1 to recite “wherein the polymorphism specific for *M. tuberculosis* in position -215 is thymine (T).” Accordingly, Applicant submits that this ground of rejection has been overcome.

Claims 19-27, 31-44 and 46-54 stand rejected under 35 U.S.C. 112, second paragraph, as indefinite. More specifically, it is asserted in the Office Action that the above claims are indefinite because they do not recite what is considered the specific *M. tuberculosis* polymorphism.

To facilitate allowance and without acquiescing to the above rejection, Applicant has amended claims 19, 20, 31 and 36 to recite “wherein the polymorphism specific for *M. tuberculosis* in position -215 is thymine (T).” Accordingly, Applicant submits that this ground of rejection against 19, 20, 31 and 36 and their dependent claims (*i.e.*, claims 21-25, 32-35, 38-44 and 51 have been overcome. In addition, as indicated above, claim 1 has been amended to recite the same language. Thus, this ground of rejection against claims 52-54 that refer to claim 1 has also been overcome.

Applicant respectfully traverses this rejection against claims 26, 27 and 46-50. Applicant submits that these claims recite specific nucleotide sequences that encompass position -215, in the 5' to 3' direction of reading, upstream of the translation start codon GTG of the *narGHJI* nitrate reductase operon. Thus, the nucleotides at position -215 are specified via the specific sequences recited in these claims. Accordingly, Applicant submits that this ground of rejection against claims 26, 27 and 46-50 has been overcome.

Claim 35 stands rejected under 35 U.S.C. 112, second paragraph, as indefinite. More specifically, it is asserted in the Office Action, this claim is indefinite due to its recitation of the word “useful.”

To facilitate allowance and without acquiescing to the above rejection, Applicant has amended claim 35 to delete the recitation of the word “useful.” Accordingly, Applicant submits that this ground of rejection against claim 35 has been overcome.

In view of the above remarks, Applicant respectfully requests that the rejections under 35 U.S.C. 112, second paragraph, be withdrawn.

Previous Rejection Under 35 U.S.C. 102(b)

Previously pending claim 28 was rejected as anticipated by Fleischmann *et al.* (U.S. Pat. No. 6,294,328, “Fleischmann”) in the Office Action dated October 28, 2008. More specifically, it is asserted in that Office Action that (1) this claim is drawn to a hybridization probe, and (2) the only requirement is that the claimed subject matter be a sequence comprising SEQ ID NO:6 or the complementary sequence thereof. It is further asserted that both SEQ ID NO:1 (at residues 1287095-1287113) and SEQ ID NO:2 (at residues 1286564-1286582) disclosed in Fleischmann comprise instant SEQ ID NO:6. Applicant canceled previously pending claim 28 to facilitate allowance and without acquiescing to the above rejection in the response filed February 27, 2009.

In the instant response, Applicant added new claim 57, which corresponds to previously pending claim 28. Applicant respectfully traverses the above rejection against previously pending claim 28 in the Office Action dated October 28, 2008. More specifically, Applicant disagrees with the assertion that previously pending claim 28 only requires that the subject matter claimed be a sequence comprising SEQ ID NO:6 or the complementary sequence thereof. Previously pending claim 28 is directed to a hybridization probe, and one of ordinary skill in the art would understand that a hybridization probe requires a detectable label (*e.g.*, a radioactive or fluorescent label) attached to a nucleic acid molecule. Fleischmann does not disclose a hybridization probe that comprises SEQ ID NO:6 or the complementary sequence

thereof. Fleischmann relates to DNA sequences for strain analysis in *M. tuberculosis*. SEQ ID NOS:1 and 2 of Fleischmann are the complete DNA sequences of the H37Rv and CDC1551 strains of *M. tuberculosis*, which are each over 4 million nucleotides in length. The method provided by Fleischmann is to evaluate the strain variation of a strain of *M. tuberculosis* of interest by (a) determining the nucleotide sequence of the strain at positions in the complete sequence of the genome that correspond to positions where *M. tuberculosis* strains CDC1551 and H37Rv differ and (b) determining whether the nucleotide sequence of the strain of interest shows greater homology at the positions to the nucleotide sequence of strain CDC1551 or H37Rv. Nowhere in Fleischmann discloses a specific hybridization probe that encompass a specific region in the genome of strain CDC1551 or H37Rv (*i.e.*, at residues 1287095-1287113 of SEQ ID NO:1 or residues 1286564-1286582 of SEQ ID NO:2). Accordingly, Applicant submits that new claim 57 (which corresponds to previously pending claim 28) is not anticipated by Fleischmann.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicant believes that the remaining claims of the present application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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